

August 12, 1999

Dockets Management Branch (HFA-305) 382 '89 13 40:06  
Food and Drug Administration  
5630 Fishers Lane rm. 1061  
Rockville, MD 20852

RE-Draft HCV Guidance Document released 6/17/99

Dear Sir or Madam:

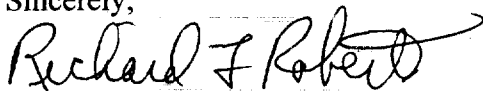
The HCV Guidance document submitted for public comment this June presents one significant omission. Omitted is the prior stipulation to lookback 10 years from the HCV positive donation or to January 1988. The consequence of the removal of this stipulation is far-reaching and will necessitate reopening and reperforming the current HCV lookback that many institutions, including blood centers and transfusion services, have completed or have underway. This additional requirement to extend lookback for an indefinite period will seriously tax an already overburdened health system, with both economic and personnel ramifications. Furthermore, the data from the HCV multi-antigen testing lookback is only now being collated and reviewed.

A general HCV education campaign advocating testing for anyone transfused prior to 1992 is in the interest of optimal patient care. We could identify those individuals that received a transfusion from a donor that never returned to the blood center for subsequent donations (and hence testing).

When requiring HCV lookback of donors newly identified with HCV infection a 'rolling' 10 year period should be employed. In this way we could concentrate our efforts on those recipients at highest risk. Since HCV testing of donor blood began in 1992 most donors possessing antibodies to HCV should have been eliminated from the donor pool and donors within the window period will also have been identified.

In closing, I encourage the FDA to retain the lookback stop date 1988 and that we complete current lookback efforts prior to undertaking HCV single antigen testing lookback. Our transfusion recipients could be better served by focusing our public health efforts toward a general HCV lookback campaign.

Sincerely,



Richard F. Roberts  
Director, Laboratory

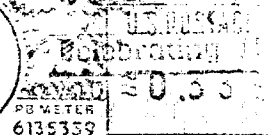
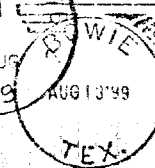
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Bowie, Texas 76230

ADDRESS CORRECTION & FORWARDING REQUESTED



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